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CHARLOTTE, NC

JUN 12 2019

US DISTRICT COURT
WESTERN DISTRICT OF NC

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA

BETTY SUE TOOMEY AND PERRY
TOOMEY,

Plaintiffs,

v.

COLOPLAST CORP.,

Defendant.

Civil Action No.: 3:19-cv-00130-RJC-DSC

AGREED PROTECTIVE ORDER

I. SCOPE OF ORDER

Disclosure and discovery in this proceeding may involve production of confidential, proprietary, and private information for which special protection from public disclosure and from any purpose other than prosecuting this litigation would be warranted. Accordingly, the parties hereby stipulate to and petition the court to enter this Agreed Protective Order in this matter.

II. THE ORDER

The parties have agreed to be bound by the terms of this Agreed Protective Order and to request its entry by the presiding judge. It is hereby ORDERED as follows:

A. DISCOVERY PHASE

1. For purposes of this Order, the following definitions shall apply: (a) the terms "document" and "electronically stored information" ("ESI") shall have the full meaning ascribed to them by the Federal Rules of Civil Procedure ("Fed. R. Civ. P."); and (b) the term "producing party" shall be defined as any party or non-

party who is required to produce or provide materials or testimony containing confidential information.

2. A producing party may designate as “**CONFIDENTIAL**” any material, including any documents or ESI, the producing party believes in good faith constitutes or discloses information that qualifies for protection pursuant to Fed. R. Civ. P. 26(c), specifically information that is trade secret or other confidential research, development, or commercial information, and materials that are deemed confidential under Federal Drug Administration (“FDA”) regulations and Health Insurance Portability and Accountability Act (“HIPAA”) statutes and/or regulations.
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3. Confidential information may be further designated as “**HIGHLY CONFIDENTIAL**” if a Defendant produces materials that it believes in good faith would, if disclosed, cause substantial economic harm to the competitive position of the entity from which the information was obtained because it is **HIGHLY CONFIDENTIAL** research and development material on a new product that has not been approved or cleared by the FDA or a similar regulatory body or reflects a party’s price competitiveness in the market or marketing business strategies of a party concerning a current or new product. The plaintiff(s) will inform the producing party of its intent to disclose such information to any individual who is currently, or who at any time during the pendency of this litigation becomes, a *consultant to a competitor* of the producing party in the pelvic organ mesh business, or is a consultant to an entity actively investigating entering such business, and

plaintiff(s) will follow the procedures for disclosure of such materials to such individual as provided in Paragraph II.A.8 of this Protective Order.

4. Challenges to Designations or Redacted Information: Any party may at any time challenge the redaction or the designation of information as **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** by providing written notice of its objection to the designating party, or, in the case of a deposition, either on the record at a deposition or in writing later. Any challenge to the confidentiality designation must be specific as to which document(s) or other material is being challenged by listing Bates numbers or other identifying information if no Bates numbers are available; categorical or blanket challenges are not permitted. If, after a meet-and-confer process, the parties cannot reach agreement, either the designating party or challenging party may, on reasonable notice, apply for an appropriate ruling from the Court. Prior to filing such a challenge, the parties must reach an agreed briefing schedule that allows the designating party a reasonable amount of time to collect supporting affidavits or other evidence in support of its confidentiality designation. The disputed material shall continue to be treated as designated, or redacted, until the Court orders otherwise—this includes any exhibits to the application to the Court, which should be filed under seal or otherwise handled in accordance with local Court procedures to prevent public disclosure until the Court orders otherwise. In any such application concerning a ruling on confidentiality or redacted information, the party claiming the designation of confidentiality or redaction has the burden of establishing that such confidential designation or redaction is proper.

5. No person or party subject to this Order shall distribute, transmit, or otherwise divulge any material marked **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL**, except in accordance with this Order. Any notes, summaries, compilations, copies, electronic images or databases containing **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** information shall be subject to the terms of this Order to the same extent as the material or information from which such notes, summaries, compilations, copies, electronic images or databases is made or derived. Nothing in this Order shall restrict a producing party's use of their own documents.
6. Use of **CONFIDENTIAL** Material Limited to this Action: Any document or other material which is marked **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL**, or the contents thereof, may be disclosed to or used by only this Court and its personnel, court reporters, deponents, a party, or a party's attorney, paralegal, expert witness, or consultant, and only for the purpose of this action or appeal therefrom. Nothing contained in this Order shall prevent the use of any document or the contents thereof, at any deposition taken in this action. If a party intends to use material that has been marked as **HIGHLY CONFIDENTIAL** at the deposition of an employee or former employee of a non-producing party in this litigation, then the party shall notify the producing party ten (10) days in advance of the deposition that it intends to use that category of material. If the parties cannot agree on parameters for usage of the material at the deposition, then the parties will seek the direction of the Court as to the utilization of that category of material in the deposition.

7. Access to **CONFIDENTIAL** Material: If a party or attorney wishes to disclose any document or other material which is marked **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL**, or the contents thereof, to any deponent or to any person actively working on, or retained to work on, this action (other than full-time employees of a party's attorney), e.g., an expert witness, or consultant, the party or attorney making the disclosure shall do the following prior to disclosing any **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** information or materials to such person:
- (a) Provide a copy of this Order to the person to whom the disclosure is to be made;
 - (b) Inform the person to whom disclosure is to be made that s/he is bound by this Order;
 - (c) Require the person to whom disclosure is to be made to sign an acknowledgment and receipt of this Order;
 - (d) Instruct the person to whom disclosure is to be made to return or, in the alternative and with permission of the producing party, at the conclusion of the case to destroy any document or other material which is marked **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL**, including notes summaries, compilations, copies, electronic images or databases made from **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** material;
 - (e) Maintain a list of persons to whom disclosure was made and the **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** materials which were disclosed to that person; and

- (f) At the conclusion of this action, gather the **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** materials, copies thereof, and related notes, summaries, compilations, copies, electronic images or databases, and return them to the party or attorney who originally disclosed them, or destroy them, providing a certificate of compliance with the terms of this Protective Order.

8. Disclosure Requirements for **HIGHLY CONFIDENTIAL** information to Competitor-Related Consultants: Prior to disclosure, plaintiff(s) will inform the producing party of its intent to disclose **HIGHLY CONFIDENTIAL** material to anyone who is currently, or who at any time during the pendency of this litigation becomes, a consultant to a competitor (as such individuals are defined in Paragraph II.A.3 above) in the manner set forth below:

- (a) Give at least ten (10) days' notice in writing to counsel for the party who designated such information as **HIGHLY CONFIDENTIAL** of the intent to so disclose that information, although the disclosing party is not required to identify the intended recipient of such materials.
- (b) Within ten (10) days thereafter, counsel for the parties shall attempt to resolve any disputes between them regarding the production of the **HIGHLY CONFIDENTIAL** material to the intended individuals.
- (c) If the parties are unable to resolve any dispute regarding such production, within an additional ten (10) days, the party who designated the information in question as **HIGHLY CONFIDENTIAL** shall file a motion objecting to the proposed disclosure. In making such motion, it shall be the producing party's burden to demonstrate good cause for preventing the disclosure.

(d) If the Court permits disclosure of the material designated as **HIGHLY CONFIDENTIAL** at issue, the information remains designated as **HIGHLY CONFIDENTIAL** and the individual receiving such information shall be bound by the requirements of Paragraph II.A.7.

9. Redaction of **CONFIDENTIAL** Material: The parties recognize that certain FDA, other governmental agencies, and certain federal statutes or regulations require redaction or non-disclosure of certain information prior to production of certain information by Defendants or agency non-disclosure of information and that Defendants will act consistently with those requirements and redact or withhold such information. Any party challenging information that has been redacted may do so in accordance with Paragraph II.A.4 of this Protective Order, or otherwise in accordance with the Federal Rules of Civil Procedure.
10. Use of **CONFIDENTIAL** Material at Depositions: All transcripts and exhibits shall be treated as if designated **CONFIDENTIAL** for a period of thirty (30) days after the final transcript is provided by the court reporter to the parties. Counsel for any party may designate during the deposition or during the thirty-day period after the final transcript is provided by the court reporter any portion of the transcript as **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** by denominating by page and line, and by designating any exhibits, that are to be considered **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** pursuant to the criteria set forth in this Order. Such designation shall be communicated to all parties. Transcript portions and exhibits designated in accordance with this paragraph shall be disclosed only in accordance with this Order, including in any motions or other papers filed in this proceeding. A

party may challenge the **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** designation or portions thereof in accordance with the provisions of Paragraph II.A.4 above.

11. Use of **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** Material in Filings:

Where any **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** information or document is included in any papers filed with the Court, such papers shall be marked in words that in substance state, “CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER IN TOOMEY V. COLOPLAST CORP., Civ. Act. No. 3:19-cv-130-RJC-DSC (W.D.N.C.),” and placed in a sealed envelope marked with the caption of the case and held under seal in accordance with the local rules and practices of this Court for such pleadings and documents.

12. Subpoenas or Discovery Requests From Other Courts or Agencies. If another court or administrative agency subpoenas or orders production of **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** information that a party has obtained under the terms of this Order, or if parties to a different action serve discovery requests on a party in this action that would require disclosure of **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** information that a party has obtained under the terms of this Order, such party shall within two (2) days of receiving the subpoena, order, or discovery request notify the producing party of the pendency of the subpoena, order, or discovery request in writing. Nothing in this paragraph authorizes any party to produce or disclose **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** information in violation of this Order.

13. Inadvertent Failure to Properly Designate **CONFIDENTIAL** Material: Inadvertent production of any document or information without a designation of **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** will not be deemed to waive a party's claim to its **CONFIDENTIAL** nature or stop said party from designating said document or information as **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** at a later date. Disclosure of said document or information by another party prior to such later designation shall not be deemed a violation of the provisions of this Order.

14. Disclosure of Privileged Documents, "Clawback" Procedure:

(a) This Order invokes the protections afforded by Federal Rule of Evidence (Fed. R. Evid.) 502(d). If a producing party produces (or discloses) to a receiving party any documents or information subject to a claim of privilege or immunity from discovery (including but not limited to attorney-client privilege, work product, and immunities created by federal or state statute or regulation), such production (or disclosure) shall not be deemed a waiver in whole or in part of the producing party's claim of privilege or immunity from discovery, either as to specific documents and information produced (or disclosed) or on the same or related subject matter, either in this case or in any other action, investigation, or proceeding. In the event that a party produces or discloses documents, ESI, or other materials subject to a claim of privilege or immunity, the producing party shall, within ten (10) days of the discovery of the production or disclosure, notify the other party in writing of the production (or disclosure) of materials protected by any privilege or

immunity. From the moment a party provides notice of production (or disclosure) of materials protected by any privilege or immunity, a receiving party shall not copy, distribute, or otherwise use in any manner the disputed documents or information, and shall instruct all persons to whom the receiving party has disseminated a copy of the documents or information that the documents or information are subject to this Order and may not be copied, distributed, or otherwise used pending further notice from the Court. The producing party may, in the notice, request a "clawback" of the produced or disclosed material. The producing party shall provide or supplement a privilege log with a description of the produced or disclosed documents within a reasonable time of providing such notice. The party receiving such clawback notice shall immediately and diligently act to retrieve the produced or disclosed documents, and all copies, including any loaded to databases, and within five (5) days return them to the producing party or destroy them as agreed between the parties. All notes or other work product of the receiving party reflecting the contents of such materials shall be destroyed and not used.

- (b) The party receiving such materials, after receipt of the producing party's notice, and within ten (10) days of receipt of the privilege log describing such documents, may move the Court to dispute the claim of privilege or immunity. If the receiving party elects to file such a motion, no use shall be made of such produced or disclosed materials in bringing the motion, nor during depositions or at trial, nor shall they be disclosed to anyone who was

not given access to them prior to the request to return or destroy them, unless otherwise ordered by the Court. Prior to filing such a motion, the parties must reach an agreed briefing schedule that allows the party claiming privilege a reasonable amount of time to collect supporting affidavits or other evidence in support of its privilege claims.

- (c) Nothing in this Order overrides any attorney's ethical responsibilities to refrain from examining or disclosing materials that the attorney knows or reasonably should know to be privileged and to inform the producing or disclosing party that such privileged material has been produced or disclosed.


B. POST DISCOVERY PHASE

1. If any party or attorney wishes to file, or use as an exhibit or as testimonial evidence at a hearing or trial, any **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** material, such party must provide reasonable notice to the producing party of the intended use of such information. The parties shall then attempt to resolve the matter of continued confidentiality by either (a) removing the **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** marking, (b) creating a mutually acceptable redacted version that suffices for purposes of the case, or (c) conferring about methods to avoid or limit public disclosure of such information during testimony. If an amicable resolution proves unsuccessful, the parties may present the issue to the Court for resolution in accordance with Paragraph II.A.4. The proponent of continued confidentiality will have the burden of persuasion that the document or material should be withheld from the public record in accordance with local rules, procedures, and governing jurisprudence.

2. Survival of Protective Order: Throughout and after the conclusion of this litigation, including any appeals, the restrictions on communication and disclosure provided for herein shall continue to be binding upon the parties and all other persons to whom **CONFIDENTIAL** and **HIGHLY CONFIDENTIAL** material has been communicated or disclosed pursuant to the provisions of this Order or any other order of the Court.
3. Return or Destruction of **CONFIDENTIAL** and **HIGHLY CONFIDENTIAL** Material Upon Termination of Litigation: Within sixty (60) days after the final termination of this action, each party, upon request of the other party, shall either return to the producing party, or destroy, all **CONFIDENTIAL** and **HIGHLY CONFIDENTIAL** material designated by any other party (including any such material disclosed to third persons), and shall destroy, should the Producing Party so request, all copies of **CONFIDENTIAL** material that contain and/or constitute attorney work product as well as excerpts, summaries and digests revealing **CONFIDENTIAL** and **HIGHLY CONFIDENTIAL** material; provided, however, that counsel may retain complete copies of all transcripts and pleadings including any exhibits attached thereto for archival purposes, subject to the provisions of this Order.
4. Modification of this Order: Nothing in this Order shall prevent any other party from seeking amendments broadening or restricting the rights of access to or the use of **CONFIDENTIAL** and/or **HIGHLY CONFIDENTIAL** material or otherwise modifying this Order; and this Order may be amended without leave of the Court by

the agreement of the undersigned attorneys for the parties in the form of a
Stipulation that shall be filed in this case.

DATE ENTERED: 6.11.19


ROBERT J. CONRAD JR.
UNITED STATES DISTRICT JUDGE

Dated: May 28, 2019

Respectfully submitted:

/s/ Eric M. Przybysz

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